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From: hochadel.m@gsm.com
Sent: Thursday, June 24, 1999 10:56 AM
To: BHINER@orahq.ora.fda.gov
Subject: Compounding Regulations-Women's Health

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Elizabeth Hiner, R.Ph.

Dockets Management Branch (HFA-305)

Docket No. 98-N-1265

Food and Drug Administration

5600 Fishers Lane

Rockville, MD 20857

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

As a health care professional who specializes in the women's health area (particularly in pregnancy, fertility, and postpartum care), I have seen the rewards of specially compounded products, including hormones, that have made healthy pregnancies possible. In many instances, products that were not available from the pharmaceutical industry allowed these families to become complete. Once a high-quality product is available on the US market from the pharmaceutical manufacturers for a specific hormonal purpose, I do believe at that point that those FDA approved products should be used preferentially. However, there are many circumstances under which titrated, patient specific hormone therapies, may provide the only acceptable option to a prescriber and his/her patient. In many instances, there are only a few specialized pharmacies, many whom are not in the local community of these patients, that can fill these types of prescriptions with care. In these instances there would be a grave disservice to American women should the FDA prohibit specialized pharmacy compounding practices. I would rather see a list of reasonable quality assurance standards or guidelines published for those pharmacies that pursue these specialized areas to follow versus a prohibition of such activities altogether.

As a pharmacist who is always providing my patients with the best quality healthcare, information, and prescription services I can, I hope you will consider my opinion in this matter. Please note that I am not in the employ of any of the types of facilities mentioned by this proposed regulation.

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